UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

ANNA PIETRANTONI, Plaintiff, v. CORCEPT THERAPEUTICS INCORPORATED and OPTIME CARE INC., Defendants.	)	CIVIL ACTION NO. 22-10072-WGY

YOUNG, D.J. November 10, 2022

MEMORANDUM & ORDER

I. INTRODUCTION

Anna Pietrantoni ("Pietrantoni") brings this action against Corcept Therapeutics Incorporated ("Corcept") and Optime Care Inc. ("Optime") (collectively, the "Defendants") for the manufacture, marketing, and distribution of Korlym, a pharmaceutical prescribed to treat Cushing's Disease. See Am. Compl. & Jury Demand ("Compl."), ECF No. 10. Pietrantoni alleges that taking Korlym caused harm to her reproductive system resulting in an emergency dilation and curettage that rendered her unable to carry a pregnancy to term. See id. ¶ 1.

Pietrantoni brings nine counts alleging negligence, misrepresentation, and breach of warranty. Distributed among these nine counts are several categories of claims: (1) Korlym is defectively designed ("**defective design**"); (2) Corcept failed

to warn consumers and physicians of the extent to which Korlym could harm the female reproductive system ("**failure to warn**") either through (A) product labeling or (B) reports to the Food and Drug Administration ("FDA"); and (3) Corcept and Optime failed to carry out their duty to monitor Pietrantoni's health while taking Korlym ("**failure to monitor**"). See generally Compl.

Corcept and Optime move to dismiss all counts on the grounds that the claims are preempted by federal law and also fail independently under state law. See Mot. Defs. Corcept & Optime Dismiss All Counts Am. Compl. ("Mot Dismiss"), ECF No. 24.

At a motion hearing on June 29, 2022, the Court **ALLOWED** the motion as to counts six and seven for failure to plead with particularity and took the remainder under advisement. See Electronic Clerk's Notes, ECF No. 46. This Memorandum addresses the outstanding claims.

With respect to the remaining counts, the motion is now **ALLOWED** in part and **DENIED** in part. The motion is ALLOWED as to counts one and three insofar as they allege defective design and failure to warn premised on product labeling; count four insofar as it alleges failure to warn premised on product labeling; count five in its entirety; count eight in its entirety; and count nine in its entirety.

The motion is DENIED as to count one insofar as it alleges negligent failure to warn premised on FDA reporting; count two in its entirety; count three insofar as it alleges grossly negligent failure to monitor; and count four, which is construed as a breach of warranty claim, insofar as it alleges failure to warn premised on FDA reporting.

II. PROCEDURAL HISTORY

Pietrantoni filed suit against Corcept and Optime on January 19, 2022. Compl. & Jury Demand ("Original Compl."), ECF No. 1. On February 17, 2022, Pietrantoni filed an amended complaint. See Compl.

She brings nine counts: negligent failure to warn and defective design against Corcept (count 1), id. ¶¶ 21-30; negligent failure to monitor against Corcept and Optime (count 2), id. ¶¶ 31-38; grossly negligent failure to warn, defective design, and failure to monitor against Corcept and Optime (count 3), id. ¶¶ 39-48; strict products liability for failure to warn (count 4), and defective design (count 5) against Corcept, id. ¶¶ 49-73; intentional and negligent misrepresentation as to the failure to warn against Corcept and Optime (count 6), id. ¶¶ 74-81; intentional and negligent misrepresentation as to the failure to monitor against Corcept and Optime (count 7), id. ¶¶ 82-87; breach of express warranty through failure to warn and

defective design against Corcept (count 8), id. ¶¶ 88-93; and breach of implied warranty through failure to warn and defective design against Corcept (count 9), id. ¶¶ 94-99.

On May 9, 2022, Corcept and Optime filed a motion to dismiss all counts. See Mot. Dismiss. The parties have fully briefed the motion. Defs.' Mem. Law Supp. Mot. Dismiss ("Defs.' Mem."), ECF No. 25; Pl.'s Mem. Opp'n Defs.' Mot Dismiss ("Pl.'s Mem."), ECF No. 36; Reply Defs. Corcept Therapeutics & Optime Support Mot. Dismiss ("Defs.' Reply"), ECF No. 39.

In conjunction with their motion to dismiss, the Defendants requested that the Court take judicial notice of five exhibits. Defs.' Req. Judicial Notice, ECF No. 26. Pietrantoni filed her own request for judicial notice, Pl.'s Mem., Ex. 1, Pl.'s Req. Judicial Notice ("Pl.'s Req. Judicial Notice"), ECF No. 36-1, which the Defendants have opposed, Defs.' Opp'n Pl.'s Req. Judicial Notice ("Defs.' Opp'n Judicial Notice"), ECF No. 40.

This Court held a hearing on the motion to dismiss on June 29, 2022. After hearing counsels' arguments, the Court **ALLOWED** the motion as to counts six and seven in their entirety for not satisfying the particularity requirements of Federal Rule of Civil Procedure 9(b). It took the remainder under advisement. See Electronic Clerk's Notes, ECF No. 46.

III. STATUTORY AND REGULATORY FRAMEWORK

A. Approval of a New Drug

The Food, Drug, and Cosmetic Act ("FDCA"), implemented and enforced by the FDA, governs the approval and labeling of prescription drugs. See 21 U.S.C. §§ 301, et seq. The FDCA requires drug manufacturers to obtain approval from the FDA before marketing a new drug. 21 U.S.C. § 355(a). To do so, manufacturers must submit a New Drug Application ("NDA") containing "full reports of [clinical] investigations" showing that the drug is safe and effective for its use. Id. §§ 355(b), (d). For approval, the NDA must prove by "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling." Id. § 355(d).

Manufacturers of a prescription drug are required to include in their NDAs "specimens of the labeling proposed to be used for such drug." Id. § 355(b). These package inserts must contain, inter alia, warnings, precautions, contraindications, and adverse reactions. 21 C.F.R. §§ 201.56, 201.57. Certain prescription drugs which "pose a serious and significant public health concern" are subject to an additional labeling requirement in that manufacturers must submit "Medication Guides" -- documents comprising additional statements of risk that must comport with package inserts. Id. §§ 208.1. The FDA

conducts a detailed review of product labeling, 21 C.F.R. §§ 201.56, 201.57, and its approval of a new drug "includes the approval of the exact text in the proposed label,". Wyeth v. Levine, 555 U.S. 555, 568 (2009) (citing 21 U.S.C. § 355; 21 C.F.R. § 314.105(b)).[1]

The FDA may approve an NDA only if clinical investigations indicate that the drug (1) is safe for its intended use, (2) will have the effect it purports to have, and (3) has labeling that is not "false or misleading in any particular." 21 U.S.C. § 355(c), (d); see also 21 C.F.R. § 314.105(c).

B. Changes to Drug Labeling

After obtaining FDA approval of a new drug, in order to alter the drug or drug label, the manufacturer must file a supplemental application. See 21 C.F.R. § 314.70(b). By default, manufacturers are required to receive prior FDA approval to make a proposed change. See id. There exists,

[1] The FDA has a measured approach to the content of warning labels, "concerned not only with avoiding insufficient warnings (that is, failing to warn against risks), but also avoiding over-warning (that is, warning against risks that are unduly speculative, hypothetical, or not adequately supported by science)." In re Zofran (Ondansetron) Prods. Liab. Litig., 541 F. Supp. 3d 164, 168 (D. Mass. 2021) (Saylor, J.). The FDA recognizes that the "exaggeration of risk, or inclusion of speculative or hypothetical risks, could discourage appropriate use," and that warnings of "theoretical hazards not well-grounded in scientific evidence can cause meaningful risk information to lose its significance." Id. at 171 (internal quotation marks and brackets omitted).

however, a path by which brand-name drug manufacturers may change a drug label without waiting for FDA approval; this is done through the "changes being effected" ("CBE") regulation. Under the CBE regulation, upon the submission of a supplemental application to the FDA, brand-name manufacturers may unilaterally implement labeling changes. See 21 C.F.R. §§ 314.70(c)(6).

Any change made pursuant to the CBE regulation must meet two requirements. See In re Celexa & Lexapro Mktg. & Sales Practices Litig., 779 F.3d 34, 37 (1st Cir. 2015). First, it must "reflect **newly acquired information**." 21 C.F.R. § 314.70(b) (emphasis added). The FDA defines "newly acquired information" as:

> data, analyses, or other information **not previously submitted** to the Agency, which may include (but is not limited to) data derived from new clinical studies, **reports of adverse events**, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events, or analyses reveal risks of a **different type** or **greater severity** or **frequency** than previously included in submissions to FDA.

Id. § 314.3 (emphasis added). Second, it must seek to achieve one of the following objectives:

> (A) To add or strengthen a **contraindication, warning, precaution, or adverse reaction** for which the evidence of a **causal association** satisfies the standard for inclusion in the labeling . . . ;
>
> (B) To add or strengthen a statement about drug abuse, dependence, psychological effect, or overdosage;

> (C) To add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product;
>
> (D) To delete false, misleading, or unsupported indications for use or claims for effectiveness; or
>
> (E) Any labeling change normally requiring a supplement submission and approval prior to distribution of the drug product that FDA specifically requests be submitted under this provision.

Id. § 314.70(c)(6) (emphasis added). After a manufacturer has made a change pursuant to the CBE regulation, the FDA retains authority retroactively to approve or reject the supplemental submission. Id. § 314.70(c)(7).

IV. REQUESTS FOR JUDICIAL NOTICE

With respect to the FDA approval processes, Corcept and Optime request that the Court take judicial notice of five exhibits:

- The FDA's February 17, 2012, NDA Approval Letter for Korlym
- Korlym's February 17, 2012, label
- Korlym's October 25, 2016, label
- The FDA's Center for Drug Evaluation and Research Medical Review(s) relating to Corcept's NDA
- Corcept's February 15, 2011, cover letter regarding submission of its NDA for Korlym

Defs.' Req. Judicial Notice 1-2. Pietrantoni does not oppose the Defendants' request but submits her own request that the Court take judicial notice of five exhibits purportedly containing data from the FDA and World Health Organization

("WHO") websites on adverse event reports associated with Korlym:

- A summary of incidents of dilation and curettage in patients taking Korlym based on data from the FDA Federal Adverse Event Reporting System ("FAERS") database
- A summary of incidents of hysterectomy in patients taking Korlym based on data from the FDA FAERS database
- A statement of the number of incidents of hysterectomy in patients taking mifepristone based on data from the WHO VigiAccess database
- A summary of incidents of endometrial thickening in patients taking Korlym based on data from the FDA FAERS database
- A statement of the number of incidents of endometrial thickening in patients taking mifepristone based on data from the WHO VigiAccess database

Pl.'s Req. Judicial Notice 1-10. Corcept and Optime oppose Pietrantoni's request on the grounds that her exhibits are summaries prepared by counsel. See Defs.' Opp'n Judicial Notice 1-2.

On a motion to dismiss, courts "consider not only the complaint but also matters fairly incorporated within it and matters susceptible to judicial notice." In re Colonial Mortg. Bankers Corp., 324 F.3d 12, 15 (1st Cir. 2003). Pursuant to the Federal Rules of Evidence, "a judge may take notice of an adjudicative fact only if it is not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." Crimson Galeria Ltd.

P'ship v. Healthy Pharms, Inc., 337 F. Supp. 3d 20, 30 (D. Mass. 2018) (Burroughs, J.) (citing Sarvis v. Polyvore, Inc., No. 12-cv-12233-LTS, 2015 WL 5934759, at *4 (D. Mass. Aug. 24, 2015)); see also Fed. R. Evid. 201(b). Matters of public record, see In re Colonial Mortg. Bankers Corp., 324 F.3d at 15-16 -- which include material on government websites, see Gent v. Cuna Mut. Ins. Soc'y, 611 F.3d 79, 84 n.5 (1st Cir. 2010) -- are generally subject to judicial notice.

Thus, this Court on several occasions has taken judicial notice of information on the FDA's website. See Gustavsen v.Alcon Labs., Inc., 272 F. Supp. 3d 241, 252 (D. Mass. 2017) (Wolf, J.) (taking judicial notice of exhibits to a plaintiff's opposition to a motion to dismiss "because all of the documents were on the FDA's website"); In re Ariad Pharm., Inc. Sec. Litig., 98 F. Supp. 3d 147, 174 (D. Mass. 2015) (taking "judicial notice of the FDA's Full Prescribing Information and the FDA [Center for Drug Evaluation and Research] report as public records"); In re Fruit Juice Prods. Mktg. & Sales Practices Litig., 831 F. Supp. 2d 507, 509 (D. Mass. 2011) (Ponsor, J.) (taking "judicial notice of three sets of facts that have been posted on the FDA's website"); Rock v. Lifeline Sys. Co., No. 13-11833-MBB, 2014 U.S. Dist. LEXIS 55611, at *33 (D. Mass. Apr. 22, 2014) (Bowler, M.J.) (taking judicial notice of FDA website printouts); In re Celexa & Lexapro Mktg. & Sales

Practices Litig., No. MDL No. 09-2067-NMG, 2015 U.S. Dist. LEXIS 77698, at *11-13 (D. Mass. June 15, 2015) (Gorton, J.) (taking judicial notice of documents, including drug labels, on the FDA website); In re Vertex Pharm., Inc., Sec. Litig., 357 F. Supp. 2d 343, 352 n.4 (D. Mass. 2005) (Saris, J.) (taking judicial notice of FDA policy on animal testing, available on the FDA website, as a matter of public record); In re Lantus Direct Purchaser Antitrust Litig., No. 16-12652-JGD, 2018 U.S. Dist. LEXIS 216240, at *17 (D. Mass. Oct. 24, 2018) (Dein, M.J.) (taking judicial notice of information on the FDA website on insulin injector pens).

Moreover, courts in our sister circuits have specifically held that FDA FAERS data is subject to judicial notice. See Ferraro Family Found., Inc. v. Corcept Therapeutics Inc., No. 19-CV-01372-LHK, 2021 U.S. Dist. LEXIS 160215, at *29-30 (N.D. Cal. Aug. 24, 2021) (taking judicial notice of FDA FAERS data); Bell v. Boehringer Ingelheim Pharm., Inc., No. 17-1153, 2018 U.S. Dist. LEXIS 90337, at *9 (W.D. Pa. May 31, 2018) (same); Rice v. Intercept Pharm., Inc., No. 21-cv-0036 (LJL), 2022 U.S. Dist. LEXIS 50277, at *27 n.4 (S.D.N.Y. Mar. 21, 2022) (same).

It is only appropriate, however, to take judicial notice of government records for the fact that they exist or contain certain information and not for the truth of the facts asserted within them. See Torrens v. Lockheed Martin Servs. Grp., Inc.,

396 F.3d 468, 473 (1st Cir. 2005); O'Hara v. Diageo-Guinness, USA, Inc., 306 F. Supp. 3d 441, 457 (D. Mass. 2018) (Wolf, J.); OrbusNeich Med. Co., Ltd., BVI v. Boston Sci. Corp., 694 F. Supp. 2d 106, 111 (D. Mass. 2010) (Tauro, J.).

Here, all five documents submitted by the Defendants are government records publicly available on the FDA website. Pietrantoni does not dispute their authenticity. This Court therefore **GRANTS** the Defendants' request for judicial notice of these documents -- for the fact that they exist, the information they comprise, and their legal effect, but not the truth of their contents.

In contrast, Pietrantoni's exhibits are not taken directly from the FDA or WHO website but rather appear to be data summaries prepared by counsel. Because these documents are not publicly available -- indeed, counsel has not even revealed its specific methodology in compiling these data -- they are not proper subjects of judicial notice. This Court accordingly **DENIES** Pietrantoni's request. The Court in its discretion, however, takes judicial notice of the existence of publicly available FDA FAERS data on adverse events associated with

Korlym -- keeping in mind the limitations of such adverse event reports.[2]

The Court declines to take judicial notice of WHO VigiAccess data. This data is not instructive in the case at bar, as it neither (1) attributes a date to each adverse event -- a detail crucial to the issue of preemption, see infra section VI.B.1.a. -- nor (2) distinguishes between Korlym's use for Cushing's Disease and generic mifepristone's use to induce an abortion, see VigiAccess, Mifepristone, WHO, www.vigiaccess.org (noting that VigiAccess presents the results for a given active ingredients but does not distinguish between brand names).

In the sections that follow, this Memorandum considers, in addition to facts alleged in the complaint, publicly available documents and data which the Court has taken judicial notice.

[2] FDA regulations disclaim any implication of causation as to the FAERS data. See 21 C.F.R. § 314.80(l) ("A report or information submitted by an applicant under this section (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the applicant or FDA that the report or information constitutes an admission that the drug caused or contributed to an adverse effect."). Moreover, the FDA website underscores that: the "[e]xistence of a report does not establish causation"; there exist "[d]uplicate and incomplete reports"; and the "[i]nformation in reports has not been verified." See FDA Adverse Event Reporting System (FAERS) Public Dashboard, https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard, (last accessed October 20, 2022).

V. FACTS ALLEGED

Korlym is a prescription pharmaceutical used to treat symptoms associated with Cushing's Disease. Compl. ¶ 95. Its active ingredient is mifepristone. At all times relevant, Corcept manufactured, marketed, and sold Korlym. Id. ¶ 1. Optime contracted with Corcept to serve as the "sole specialty pharmacy and exclusive distributor" of Korlym to patients. Id.

A. Korlym's Approval and Labeling

In reviewing Corcept's NDA, the FDA Center for Drug Evaluation and Research prepared a Medical Review of the risks and benefits, efficacy, and safety of Korlym (the "Medical Review"). Defs.' Req. Judicial Notice, Ex. D, FDA's Center Drug Evaluation & Research Medical Review ("FDA Medical Review"), ECF No. 26-4. The Medical Review, authored prior to the FDA's approval of Korlym, contained data from clinical trials in which users of Korlym experienced **endometrial thickening**, see id. 12 ("Increase in endometrial thickening was common in the Cushing's syndrome studies and was reported in up to 30% of females, although only a few of them had vaginal bleeding."); id. 129 ("Mifepristone and other progesterone receptor modulator drugs induce well-known progesterone receptor modulator-associated endometrial changes (PAEC) including endometrium thickening . . . ."); id. 130 ("Increase in endometrial thickness was a common adverse event in women treated with Korlym and occurred in 10 of

35 females (30%) enrolled in the study."); underwent **dilation and curettage**, see id. 131 ("[Transvaginal ultrasound] showed endometrial thickness of 55 mm. The thickness decreased to 5 mm after dilation and curettage."); id. ("Most episodes of bleeding resolved without treatment; patient underwent dilation and curettage once."); id. 132 ("Patient underwent a D&C . . . ."); and suffered **vaginal bleeding that resulted in hysterectomy**, see id. 130 ("Subject # 11-001 underwent hysterectomy"); id. ("Vaginal bleeding resulted in gynecological procedures to treat the bleeding in four subjects; three of these subjects ultimately elected to have hysterectomies in order to continue Korlym treatment."); id. 131 ("Eventually [endometrial] thickness resolved, but the subject elected to have a hysterectomy"); id. 132 ("Eventually [endometrial] thickness resolved, but the subject elected to have a hysterectomy"); id. ("Vaginal bleeding reoccurred . . . . The subject elected to have a hysterectomy").

The FDA approved Corcept's NDA for Korlym on February 17, 2012. See Defs.' Req. Judicial Notice, Ex. A, NDA Approval Letter ("NDA Approval Letter"), ECF No. 26-1. The NDA approval letter sanctioned Korlym "for the control of hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose

intolerance and have failed surgery or are not candidates for surgery." Id. 1.

From the time of approval, Korlym's label contained warnings with respect to vaginal bleeding and endometrial changes. In the Highlights section, the label stated:

> **HIGHLIGHTS OF PRESCRIBING INFORMATION . . .**
>
> **WARNINGS AND PRECAUTIONS . . .** Vaginal bleeding and endometrial changes: Women may experience endometrial thickening or unexpected vaginal bleeding. Use with caution if patient also has a hemorrhagic disorder or is on anti-coagulant therapy (5.3) . . . .
>
> **ADVERSE REACTIONS . . . .** Most common adverse reactions in Cushing's syndrome (≥20%): . . .. endometrial hypertrophy.

Defs.' Req. Judicial Notice, Ex. B, Korlym's 2012 Label ("Korlym's 2012 Label") 1, ECF No. 26-2. The Full Prescribing Information section specified:

> **FULL PRESCRIBING INFORMATION . . .**
>
> **WARNINGS AND PRECAUTIONS . . . 5.3 Vaginal Bleeding and Endometrial Changes . . .** Being an antagonist of the progesterone receptor, mifepristone promotes unopposed endometrial proliferation that may result in endometrium thickening, cystic dilatation of endometrial glands, and vaginal bleeding. Korlym should be used with caution in women who have hemorrhagic disorders or are receiving concurrent anticoagulant therapy. Women who experience vaginal bleeding during Korlym treatment should be referred to a gynecologist for further evaluation. . .
>
> **ADVERSE REACTIONS . . . 6.3 Vaginal Bleeding and Endometrial Changes . . .** In Study 400, the thickness of the endometrium increased from a mean of 6.14 mm at baseline (n=23) to 15.7 mm at end-of-trial (n=18) in premenopausal women; in postmenopausal women the

> increase was from 2.75 mm (n=6) to 7.35 mm (n=8). Endometrial thickness above the upper limit of normal was reported in 10/26 females who had baseline and end-of-trial transvaginal ultrasound (38%). The endometrial thickness returned to the normal range in 3 out of 10 patients 6 weeks after treatment cessation at the end of the study. Vaginal bleeding occurred in 5 out of 35 females (14%).

Korlym's 2012 Label 5, 8. Finally, Korlym's Medication Guide instructed:

> **Medication Guide** . . .
>
> **Do not take Korlym if you:** . . . are a woman who still has her uterus (womb) **and** have:
> - unexplained bleeding from your vagina
> - changes in the cells lining your uterus (endometrial hyperplasia) or cancer of the lining of your uterus (endometrial cancer) . . .
>
> **Korlym can cause serious side effects including:** . . . **bleeding from the vagina.** Korlym may cause the lining of your uterus to become thick and may cause your uterus to bleed. Tell your doctor right away about any bleeding from your vagina that is not normal for you.
>
> The most common side effects of Korlym include . . .
> - thickening of the lining of the uterus (endometrial hypertrophy)

Korlym's 2012 Label 1-5.

The FDA website indicates that Korlym's label underwent a revision in 2016; each of the above warnings, however, remained on the label post-revision. See Defs.' Req. Judicial Notice, Ex. C, Korlym's 2016 Label 1, 5, 8, 18, 20, 21, ECF No. 26-3. Korlym's label does **not** contain warnings about missed menstrual cycles, scar tissue, dilation and curettage, hysterectomy, or

the effect that use of Korlym could have on child-bearing. See generally id.

B. Korlym's Adverse Events

Between February 17, 2012 -- when Korlym was approved, see NDA Approval Letter 7 -- and February 2019 -- when Pietrantoni was taken off Korlym, see Compl. ¶ 14 -- the FDA FAERS database reports: (1) six cases of dilation and curettage in patients taking Korlym for Cushing's Disease; (2) eight cases of dilation and curettage in patients taking mifepristone to induce an abortion; (3) eleven to thirteen[3] cases of hysterectomy[4] and one radical hysterectomy in patients taking Korlym for Cushing's Disease; (4) two cases of hysterectomy in patients taking mifepristone to induce an abortion; (5) forty-six to fifty-eight cases of endometrial thickening or hypertrophy in patients

[3] Because some FAERS entries do not contain incident dates, the precise number of adverse events within the relevant period is uncertain.

[4] Pietrantoni seeks judicial notice of data on incidents of hysterectomy. Corcept and Optime assert that this data is "irrelevant," as Pietrantoni herself never underwent a hysterectomy. Defs.' Reply 2-3. Pietrantoni counters that "dilation and curettage and hysterectomy are on a continuum of surgical interventions" related to "severe endometrial [hypertrophy]"; thus, adverse event reports of hysterectomy tend to show "that use of Korlym could necessitate a dilation and curettage." Pl.'s Mem. 12. This Court agrees with Pietrantoni and takes notice of FDA FAERS data on incidents of hysterectomy as related to the risk of dilation and curettage.

taking Korlym for Cushing's disease. See FDA Adverse Event Reporting System (FAERS), https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/7a47a261-d58b-4203-a8aa-6d3021737452/state/analysis (last accessed October 20, 2022).

C. Pietrantoni's Use of Korlym

In April 2018, Pietrantoni was prescribed Korlym for Cushing's Disease by a physician assistant. Compl. ¶ 6. Optime shipped the medication to her. Id. ¶ 7. Corcept assigned Pietrantoni "Patient Care Advocates" who, Corcept informed, would monitor her health condition in light of taking Korlym. Id. ¶¶ 7-11. The Patient Care Advocates were to work with Pietrantoni and Optime through Optime's Support Program for Access and Reimbursement for Korlym. Id. ¶¶ 8, 10.

In Pietrantoni's first three to four months on Korlym, she and Renee -- her first Patient Care Advocate -- communicated twice per month, but communication later became less frequent. Id. ¶ 11. During their calls, Renee asked Pietrantoni about her blood pressure and potassium levels. Id.

During the first month of taking Korlym, Pietrantoni stopped having menstrual periods. Id. ¶ 12. She informed Renee, who did not instruct her to seek medical care for her reproductive system or to discontinue use. Id. "[S]everal more times over the course of the next several months," Pietrantoni informed Renee and her second Patient Care Advocate, Anna, that

she no longer had a menstrual period, but neither Renee nor Anna ever instructed her to seek medical care for her reproductive health, to stop taking Korlym, or "to have an ultrasound of any portion of her reproductive system." Id. ¶¶ 12-13.

In February 2019, a physician took Pietrantoni off Korlym "because of hormonal imbalances, including high testosterone levels." Id. ¶ 14. On March 28, 2019, Pietrantoni had a CT scan which indicated "that her uterus and ovaries were enlarged, [her] ovaries had follicles/cysts[,] and [her] uterus was filed with fluid that was ultimately identified as blood." Id. ¶ 15. In April and May, she "experienced heavy menstrual bleeding," had an ultrasound, and underwent an emergency dilation and curettage -- a procedure to remove tissue from inside the uterus. Id. Given the scar tissue from the dilation and curettage, Pietrantoni was "informed that she most likely cannot carry a pregnancy to term." Id. ¶ 16. She became pregnant and miscarried in May 2021. Id.

VI. ANALYSIS

Pietrantoni's claims against Corcept and Optime divide into three categories: (1) defective design, (2) failure to warn, and (3) failure to monitor. The failure-to-warn claims subdivide into allegations premised on Corcept's (A) product labeling and (B) reporting to the FDA.

First, as to **defective design**, Pietrantoni alleges negligent design defect (count one), grossly negligent design defect (count three), strict products liability (count five), breach of express warranty (count eight), and breach of implied warranty (count nine). Pietrantoni has represented that she would voluntarily dismiss these claims. See Pl.'s Mem. 12, 14, 19. Accordingly, the motion to dismiss is ALLOWED as to the defective design claims in counts one, three, five, eight, and nine.

Second, as to **failure to warn** through **product labeling**, Pietrantoni alleges negligent failure to warn (count one), grossly negligent failure to warn (count three), strict products liability (count four), breach of express warranty (count eight), and breach of implied warranty (count nine). Corcept and Optime argue these claims are preempted by federal law. See Defs.' Mem. 9-11. To avoid preemption, post-marketing failure-to-warn claims must show that a drug manufacturer could have independently changed the warning label without prior FDA approval. See Wyeth, 555 U.S. at 583; PLIVA, Inc. v. Mensing, 564 U.S. 604, 617 (2011). Pietrantoni has failed to allege any "newly acquired information" which would have permitted Corcept unilaterally to change Korlym's warning label. In re Celexa & Lexapro, 779 F.3d at 41 (citing 21 C.F.R. § 314.70(c)). Thus, the motion to dismiss is ALLOWED as to the claims for failure to

warn through product labeling in counts one, three, four, and nine. With respect to count eight only, Pietrantoni agreed in her briefing to dismiss the count in its entirety, see Pl.'s Mem. 19, so the motion is also ALLOWED as to count eight.

Third, as to **failure to warn** through **FDA reporting**, Pietrantoni alleges negligent failure to warn (count one) and strict products liability, which this Court construes as a breach of implied warranty claim (count four), see Mavilia v. Stoeger Indus., 574 F. Supp. 107, 109 (D. Mass. 1983) (Garrity, J.). The First Circuit has certified the question to the Massachusetts Supreme Judicial Court of whether state law recognizes a right of action against manufacturers for failing to disclose adverse event information to the FDA. See Plourde v. Sorin Grp. USA, Inc., 23 F.4th 29, 37 (1st Cir. 2022); Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 349 (2001). As the matter remains pending, dismissal would be premature. The motion to dismiss is therefore DENIED as to the claims for failure to warn through FDA reporting in counts one and four.

Fourth, as to **failure to monitor**, Pietrantoni alleges negligent failure to monitor (count two) and grossly negligent failure to monitor (count three). In Massachusetts, an entity may voluntarily assume a duty it would not otherwise have, see Cottam v. CVS Pharmacy, 436 Mass. 316, 323-24 (2002), and

Pietrantoni has plausibly alleged that Optime and Corcept assumed a duty to monitor her health while taking Korlym. Thus, the motion to dismiss is DENIED as to the failure-to-monitor claims in counts two and three.

A. Pleading Standard

To withstand a motion to dismiss, a complaint must "state a claim upon which relief can be granted . . . ." Fed. R. Civ. P. 12(b)(6). The complaint must include sufficient factual allegations that, accepted as true, "state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). Courts "draw every reasonable inference" in favor of the plaintiff, Berezin v. Regency Sav. Bank, 234 F.3d 68, 70 (1st Cir. 2000), but they disregard statements that "merely offer legal conclusions couched as fact or threadbare recitals of the elements of a cause of action," Ocasio-Hernández v. Fortuño-Burset, 640 F.3d 1, 12 (1st Cir. 2011) (brackets, ellipsis, and quotations omitted).

B. Failure to Warn

Pietrantoni claims that Corcept and Optime failed to warn physicians and consumers of the risks Korlym posed to the female reproductive system. Failure-to-warn claims may be premised on either (1) the drug's warning labels, or (2) the drug manufacturer's disclosures to the FDA. Pietrantoni's complaint

implicates both theories of liability; this Memorandum will address each in turn.

1. Failure to Warn Through Product Labeling

Pietrantoni brings several failure-to-warn claims predicated, at least in part, on product labeling: count one alleges negligent failure to warn, Compl. ¶¶ 21-30; count three alleges grossly negligent failure to warn, id. ¶¶ 39-48; count four alleges strict products liability based on failure to warn, id. ¶¶ 49-63; count eight alleges breach of express warranty, id. ¶¶ 88-93; and count nine alleges breach of implied warranty, id. ¶¶ 94-99. Corcept and Optime argue these claims are preempted, as Corcept could not have unilaterally added the desired warning to the Korlym label pursuant to FDA regulations. See Defs.' Mem. 9-11. The Defendants are correct; the failure-to-warn claims premised on product labeling are preempted by federal law.

a. The Law on Preemption

Pursuant to the Supremacy Clause of the United States Constitution, federal law "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., Art. VI, cl. 2. Thus, when "state and federal law 'directly conflict,' state law must give way." PLIVA, 564 U.S. at 617 (2011) (quoting Wyeth, 555 U.S. at 583 (2009) (Thomas, J., concurring)). State and federal

law directly conflict "where it is 'impossible for a private party to comply with both state and federal requirements.'" Mutual Pharmaceutical Company v. Bartlett, 570 U.S. 472, 480 (2013) (quoting English v. General Elec. Co., 496 U. S. 72, 79 (1990)). "Impossibility pre-emption is a demanding defense," Wyeth, 555 U.S. at 573; it turns on "whether the private party could independently do under federal law what state law requires of it," PLIVA, 564 U.S. at 620.

Four times in recent history the Supreme Court has addressed the issue of federal preemption in the context of state-law claims against drug manufacturers alleging failure to warn through product labeling.

The first -- Wyeth v. Levine, 555 U.S. 555 (2009) -- involved a brand-name drug manufacturer. In Wyeth, a jury had found the manufacturer liable for inadequate warnings on the label of Phenergan, an FDA-approved drug. Id. at 559-60. The manufacturer claimed impossibility preemption, arguing that federal regulations requiring FDA approval before making changes to drug labels rendered it impossible to discharge its state-law obligation of adding a stronger warning to Phenergan's label. Id. at 568-69. The Supreme Court dismissed this argument on the basis of the CBE regulation: through the CBE process, the manufacturer could have independently strengthened the warnings on Phenergan's label without receiving prior FDA-approval. See

id. at 571. The manufacturer argued that the CBE regulation only allows for changes that "reflect newly acquired information," id. at 568-69, but the Supreme Court rejected this "cramped reading" and deemed the CBE process available to the manufacturer. Therefore, "absent clear evidence that the FDA would not have approved a change," it was not impossible to comply with federal and state law, so the state-law claims were not preempted. Id. at 571-73.

The second and third occasions -- PLIVA, Inc. v. Mensing, 564 U.S. 604, 617 (2011) and Mutual Pharmaceutical Company v. Bartlett, 570 U.S. 472, 480 (2013) -- involved generic drug manufacturers.

In PLIVA, the plaintiffs brought state-law claims against manufacturers for failing "to provide adequate warning labels for generic metoclopramide." 564 U.S. at 608-09. The Supreme Court distinguished PLIVA from Wyeth: unlike in Wyeth, the manufacturers in PLIVA could not independently strengthen their warning labels, as generic drug manufacturers (1) must keep their warning labels identical to the brand-name drug manufacturers' labels, and (2) cannot utilize the CBE regulation to make unilateral changes to drug labels. See id. at 613-18. Thus, it was impossible for the manufacturers to comply with "both their state-law duty to change the label and their federal law duty to keep the label the same." Id. at 618. In so

holding, PLIVA limited Wyeth to circumstances in which a drug manufacturer could, in compliance with FDA regulations, make a labeling change "of its own volition." See id. at 618, 624.

The Supreme Court in Bartlett confirmed PLIVA's central holding -- that "failure-to-warn claims against generic manufacturers are pre-empted by the FDCA's prohibition on changes to generic drug labels." 570 U.S. at 479. The First Circuit had attempted to distinguish from PLIVA, holding that it was possible for a generic drug manufacturer to comply with both state and federal law by simply leaving the market altogether. Id. at 479, 489. The Supreme Court squarely rejected this maneuver, as it "would mean that the vast majority -- if not all -- of the cases in which the Court has found impossibility pre-emption, were wrongly decided." Id. at 489.

The fourth and final case was Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668 (2019). Merck involved an uncertainty that had been looming since Wyeth: whether preemption was a question of law for a judge or a question of fact for a jury. Id. at 1676. Wyeth had indicated that, even where the CBE regulation was available to a manufacturer, state-law claims would be preempted by the FDCA where there was "clear evidence" that the FDA would not have approved the warning sought. See 555 U.S. at 571. The Supreme Court in Merck clarified that "clear evidence" is **not** an evidentiary standard; the issue of

FDA approval, like preemption in general, is a question of law for a judge, even where it subsumes significant factual disputes. 139 S. Ct. at 1678-79. The Merck Court then defined "clear evidence" as "evidence that shows the court that the drug manufacturer fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning." Id. at 1668.

Lower courts have taken these four Supreme Court cases and woven an analytical framework comprising two means of establishing preemption.

First, the First Circuit has observed that Wyeth and PLIVA drew a line "between changes that can be independently made using the CBE regulation and changes that require prior FDA approval," dictating that claims seeking the latter are preempted. In re Celexa & Lexapro, 779 F.3d at 41. This line is sensible: "hinging preemption on the availability of [the CBE] procedure" to cure a particular labeling defect "effectively reserves the launch of new drugs to the expertise of the FDA, but" still allows states to "requir[e] manufacturers to respond to information not considered by the FDA." Id. Thus, to overcome a preemption defense, a complaint must "allege[] a labeling deficiency that [the manufacturer] could

have corrected using the CBE regulation." In re Celexa & Lexapro, 779 F.3d at 41.

Merck, however, furnished a second avenue to preemption -- even where the CBE process was not foreclosed to the manufacturer. Another session of this Court described Merck as establishing "a two-prong test" for preemption whereby a drug manufacturer must show that, although the CBE process was available to it in theory, "(1) it [had] fully informed the FDA of the justifications for the warning required by state law and (2) the FDA [had], in turn, informed the drug manufacturer that the FDA would not approve changing the drug's label to include that warning." In re Zofran (Ondansetron) Prods. Liab. Litig., 541 F. Supp. 3d 164, 193 (D. Mass. 2021) (Saylor, J.) (internal quotation marks and brackets omitted).

Taken together, the following framework emerges from precedent:

> [A] drug manufacturer may prevail on a preemption defense if (1) **the CBE process was not available**, and therefore it could not make unilateral changes to the label, **or** (2) it establishes by 'clear evidence' that **the FDA would not have approved the changes to the label** that the plaintiffs contend should have been made.

Id. at 195 (emphasis added). Here, the Court need only reach the first means of establishing preemption, as Corcept has shown that the CBE process was not available to it.

b. Whether the CBE Process Was Available to Corcept

As discussed, see supra section III.B., any labeling change pursuant to the CBE regulation must (1) "reflect newly acquired information" and (2) be made to accomplish at least one of five listed objectives, see In re Celexa & Lexapro, 779 F.3d at 37. The parties' dispute centers on the first prong: the Defendants assert that Pietrantoni has failed to identify any "newly acquired information" that would have permitted Corcept to amend the label under the CBE regulation, see Def.'s Mem. 14, while Pietrantoni counters that post-marketing adverse event reports are sufficient to constitute "newly acquired information," see Pl.'s Mem. 17.

FDA regulations define "newly acquired information" as:

> "data, analyses, or other information not previously submitted to the Agency, which may include (but is not limited to) data derived from new clinical studies, reports of **adverse events**, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events, or analyses **reveal risks of a different type or greater severity or frequency** than previously included in submissions to FDA.

21 C.F.R. § 314.3 (emphasis added).

The Wyeth Court took a liberal view of "newly acquired information." There, the plaintiff presented evidence that, after the manufacturer had altered Phenergan's label to reflect the risk of gangrene and amputation, "amputations continued to occur." 555 U.S. at 569-70. The Supreme Court reasoned that

the manufacturer "could have analyzed the accumulating data and added a stronger warning about IV-push administration of the drug" pursuant to the CBE regulation. See id. at 570. It thus refused to overturn a jury verdict on the basis of preemption.

Lower courts since Wyeth, however, have taken a notably more restrictive approach. The First Circuit is one example. In In re Celexa and Lexapro, the plaintiffs claimed the efficacy discussion on Lexapro's drug label was "misleading and inadequate" as to the treatment of major depressive disorder in adolescents. 779 F.3d at 38-39. The First Circuit "scrutinized the complaint itself to see if it might plausibly be read as relying on 'newly acquired information.'" Id. at 42. It dismissed the first study the plaintiffs put forth for not relating specifically to adolescents. Id. It discarded the second study -- an opinion piece arguing the FDA should not have approved Lexapro -- for failing to state any information that the FDA did not have at the time of approval. Id. Finally, it rejected the plaintiffs' allegations that a study upon which the FDA relied improperly included certain subjects in the data pool -- again for failing to allege information that was unknown to the FDA prior to approval. Id. at 42-43. Given the dearth of "new" information, the manufacturer could not have used the CBE process, so the claims were preempted. Id. at 43.

Other circuits agree that "newly acquired information" must be **information the FDA lacked when it approved the drug.** See Gibbons v. Bristol-Myers Squibb Co., 919 F.3d 699, 708 (2d Cir. 2019) (holding that the plaintiffs' "conclusory and vague" allegations regarding new studies "do not plausibly allege the existence of newly acquired information," as they do not reveal "risks of a different type or greater severity or frequency than previously included in submissions to the FDA"); Knight v. Boehringer Ingelheim Pharm., Inc., 984 F.3d 329, 338 (4th Cir. 2021) (holding that a study did not constitute "newly acquired information" since the FDA was already aware of the correlation between the drug's blood concentration levels and bleeding risk); Dolin v. GlaxoSmithKline LLC, 901 F.3d 803, 815-16 (7th Cir. 2018) (reversing a lower court and holding that a new article based on old data did not constitute "newly acquired information").

In addition to being "new" to the FDA, a manufacturer may only propose a change through the CBE process predicated on information that is "based on reasonable evidence." Merck, 139 S. Ct. at 1679. Specifically, the CBE regulation requires "reasonable evidence of a **causal association**" between the drug and "clinically significant adverse reactions." See 21 C.F.R. §§ 201.57(c)(6) (emphasis added). The Supreme Court has expressly recognized this requirement in the context of federal

preemption. See Merck, 139 S. Ct. at 1679 (stating that the "CBE regulation permits drug manufacturers to change a label to 'reflect newly acquired information' if the changes 'add or strengthen a . . . warning' for which there is **'evidence of a causal association'**" (emphasis added)).

Here, Pietrantoni alleges that Korlym's label contains inadequate warnings because of Corcept's:

> Failure to use **post marketing information** obtained through **adverse event reporting** to change the warning regarding the harm that Korlym caused to the female reproductive system . . . including . . . [the] need for a **hysterectomy** or [**dilation and curettage**] that could result in sterilization and the inability to bear children and carry a pregnancy to term.

Compl. ¶ 24(z). The complaint itself contains no greater detail as to the allegation of "post marking information obtained through adverse event reporting." Id. As discussed, however, see supra section II.C., in examining the issue of "newly acquired information," the Court will consider post-marketing adverse event reports in the FDA FAERS database with respect to endometrial thickening, dilation and curettage, and hysterectomy in patients using Korlym.

For two reasons, these adverse event reports nevertheless fail to establish the existence of "newly acquired information."

First, FAERS adverse event reports do not represent "that the drug **caused** or contributed to an adverse effect," 21 C.F.R. § 314.80(l) (emphasis added); indeed, the FDA website expressly

disclaims any causal associations with respect to its FAERS data. See FDA Adverse Event Reporting System (FAERS) Public Dashboard, https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard(last accessed October 20, 2022). The First Circuit has accordingly recognized that the "receipt of an adverse report does not in and of itself show a causal relationship between a drug and the illness mentioned in a report." United States ex rel. Ge v. Takeda Pharm. Co., 737 F.3d 116, 120 (1st Cir. 2013). Where adverse events reports are silent on matters of causation, most courts have held that these events cannot qualify as "newly acquired information." See Gayle v. Pfizer Inc., 452 F. Supp. 3d 78, 88 (S.D.N.Y. 2020) (holding that "6,000 adverse event reports relating to diabetes sent from Pfizer to the FDA" do not constitute "newly acquired information" because they do not indicate casual association); Utts v. Bristol-Myers Squibb Co., 251 F. Supp. 3d 644, 663-65 (S.D.N.Y. 2017) (holding that a written report that relies on FDA FAERS data does not constitute "newly acquired information"); Ignacuinos v. Boehringer Ingelheim Pharm., Inc., 490 F. Supp. 3d 533, 543 (D. Conn. 2020) (holding that adverse event reports are not "newly acquired information" unless they are "grounded in scientific research" such that they "provide reasonable evidence of a causal association"); McGrath v. Bayer

Healthcare Pharm., Inc., 393 F. Supp. 3d 161, 169 (E.D.N.Y. 2019) (holding that "reports and studies that discuss the fact of" adverse events but do not indicate a causal connection are not "newly acquired information"). Pietrantoni has failed to identify any case in which a court has held that FAERS adverse event reports alone qualified as "newly acquired information" permitting a manufacturer to initiate changes under the CBE regulation.

In response to this apparent shortcoming, Pietrantoni argues that there is a "known and admitted causal relationship between use of Korlym and endometrial [hypertrophy]"; the FAERS data thus indicates "numerous instances of dilation and curettage that [were] necessitated by the endometrial [hypertrophy] caused by Korlym." Pl.'s Mem. 11. That is simply not what the FAERS data shows. Even accepting that there is, in general, a causal relationship between Korlym and endometrial hypertrophy, the causal chain is incomplete; it remains open whether, in the circumstances of each adverse event report, Korlym -- and no other pre-condition or medication -- was the cause of endometrial hypertrophy, and endometrial hypertrophy -- and no other condition or diagnostic purpose --necessitated the particular dilation and curettage. See FDA Adverse Event Reporting System (FAERS) Public Dashboard, https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-

event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard (last accessed October 20, 2022) ("For any given report . . . the event may have been related to the underlying disease being treated, or caused by some other drug being taken concurrently, or occurred for other reasons.").

Second, notwithstanding causation, the FDA FAERS data still fails to satisfy the requirements of "newly acquired information." The parties agree that the only relevant data points are adverse events which took place between February 17, 2012 -- when Korlym was approved -- and February 2019 -- when Pietrantoni was taken off Korlym. See Pl.'s Mem. 10; Def.'s Mem. 10. In that time, as to patients taking Korlym for Cushing's Disease, the FDA FAERS database reveals eleven to fourteen incidents of hysterectomy or radical hysterectomy, six incidents of dilation and curettage, and forty-six to fifty-eight incidents of endometrial thickening or hypertrophy.[5] See FDA Adverse Event Reporting System (FAERS), https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard(last accessed October 20, 2022). This data, however, does not "reveal risks of a different type or

[5] For the same time period, in patients taking mifepristone to induce an abortion, the FDA FAERS database indicates two incidents of hysterectomy and eight incidents of dilation and curettage.

greater severity or frequency" than previously known to the FDA. See 21 C.F.R. § 314.3.

As to endometrial thickening or hypertrophy, these reports do not expose any risks that were unknown to the FDA at the time it approved Korlym. The Medical Review authored by the FDA itself in connection with Corcept's NDA contained results from a clinical trial finding that "endometrial thick[ening] was a common adverse event in women treated with Korlym" -- indeed, it "occurred in 10 of 35 females (30%) enrolled in the study." FDA Medical Review 130; see also id. 12, 129. Thus, unsurprisingly, the "Highlights" section of Korlym's label warns of a high frequency of endometrial thickening. See Korlym's 2012 Label 2 ("Most common adverse reactions in Cushing's syndrome (≥20%): . . .. endometrial hypertrophy."); id. ("Women may experience endometrial thickening or unexpected vaginal bleeding."). The Full Prescribing Information contains similar warnings, see id. 5 ("[M]ifepristone promotes unopposed endometrial proliferation that may result in endometrium thickening."); id. 8 ("Endometrial thickness above the upper limit of normal was reported in 10/26 females who had baseline and end-of-trial transvaginal ultrasound (38%)."), as does the Medication Guide, see id. 21 ("The most common side effects of Korlym include . . . thickening of the lining of the uterus (endometrial hypertrophy).").

As to dilation and curettage and hysterectomy, the data is similarly deficient. These adverse event reports could be material in three ways: (1) as revealing "a different type" of risk -- surgical intervention; (2) as revealing a "greater severity" of risk -- that endometrial thickening could be so serious as to require these surgical interventions; or (3) as revealing a greater frequency of risk.

The first two theories fail, however, because the risk that dilation and curettages or hysterectomies occur in patients taking Korlym does not appear to be new to the FDA. Indeed, the FDA's Medical Review contains data from clinical trials demonstrating that some users of Korlym underwent dilation and curettages and hysterectomies. See FDA Medical Review 131 ("[Transvaginal ultrasound] showed endometrial thickness of 55 mm. The thickness decreased to 5 mm after dilation and curettage."); id. ("Most episodes of bleeding resolved without treatment; patient underwent dilation and curettage once."); id. at 132 ("Patient underwent a D&C . . . ."); id. at 130 ("Subject # 11-001 underwent hysterectomy"); id. ("Vaginal bleeding resulted in gynecological procedures to treat the bleeding in four subjects; three of these subjects ultimately elected to have hysterectomies in order to continue Korlym treatment."); id. at 131 ("Eventually [endometrial] thickness resolved, but the subject elected to have a hysterectomy"); id. at 132

("Eventually [endometrial] thickness resolved, but the subject elected to have a hysterectomy"); id. ("Vaginal bleeding reoccurred . . . . The subject elected to have a hysterectomy").

The third theory fails because the FDA FAERS data indicates only eleven to fourteen cases of hysterectomy and six cases of dilation and curettage over a span of seven years. While not to be discounted, this data nevertheless suggests that these reproductive consequences are not occurring with a significantly "greater . . . frequency" than at the time the FDA approved Korlym. See 21 C.F.R. § 314.3.

In sum, Pietrantoni's failure-to-warn claims premised on product labeling lack the requisite allegations of "newly acquired information" to overcome a preemption defense. The claims are therefore preempted.

2. Failure to Warn Through Reports to the FDA

Although the thrust of Pietrantoni's complaint goes to product labeling, Pietrantoni also alleges a separate theory of liability for inaccurate or incomplete disclosures to the FDA. Pietrantoni brings two failure-to-warn claims premised, at least in part, on Corcept's failure to timely report facts relevant to Korlym's adverse health consequences to the FDA: count one alleges negligence, see Compl. ¶¶ 24(o), 24(r); and count two alleges strict products liability, id. ¶ 55, which this Court

construes as a breach of warranty claim.[6] The Defendants assert these claims are preempted, and that, regardless, they fail on the merits. See Defs.' Mem. 1-2; 10-11; 17.

Since a matter central to these claims is currently pending before the Massachusetts Supreme Judicial Court, Plourde, 23 F.4th 29, it would be premature to dismiss these allegations as preempted or otherwise insufficient; accordingly, Pietrantoni's failure-to-warn claims premised on FDA reporting may proceed.

a. The Law on Preemption

State-law claims that implicate the duty of manufacturers to communicate safety information to the FDA raise their own set of preemption concerns. The FDCA contains disclosure requirements, as well as "various provisions aimed at detecting, deterring, and punishing false statements." Buckman Co., 531 U.S. at 349. As to these requirements, the FDA "has at its disposal a variety of enforcement options," see id. at 347, and any action to enforce the FDCA must "be by and in the name of the United States," 21 U.S.C. § 337. Given this framework, the Supreme Court in Buckman Co. v. Plaintiffs' Legal Committee held

[6] Massachusetts does not have a "separate doctrine of strict products liability," Mavilia, 574 F. Supp. at 109, but instead has "expand[ed] the scope of warranty protections into a remedy intended to be comprehensive of strict liability," Jackson v. Johnson & Johnson & Janssen Pharm., Inc., 330 F. Supp. 3d 616, 626 (D. Mass. 2018) (Casper, J.).

that state-law claims against a medical device manufacturer for making fraudulent representations to the FDA in receiving approval for a new device are preempted, as they "conflict with the FDA's responsibility to police fraud." 531 U.S. at 350.

The Buckman Court differentiated "fraud-on-the-agency claims" from claims "relying on traditional state tort law," deeming only the former preempted. See 531 U.S. at 353. For this reason, the First Circuit has determined that "a state-law claim based on 'traditional state tort law' that happens to 'parallel' the FDCA is outside of [section] 337(a)'s preemptive scope." Plourde, 23 F.4th at 33. In contrast, "any state-law claim that exists 'solely by virtue of an FDCA infraction' -- like, for example, a claim against a manufacturer for violating the FDCA's ban on making false statements to the FDA during the PMA process" -- is preempted. Id. Pietrantoni has represented that she would voluntarily dismiss any "fraud on the FDA claims," see Pl.'s Mem. 17; the question is whether Pietrantoni's claims are rooted in the theory of "fraud-on-the-FDA" or, instead, in "traditional state tort law," Plourde, 23 F.4th at 33.

b. Whether Pietrantoni's Claims Are Rooted in Traditional State Tort Law

In Plourde v. Sorin Group, the plaintiffs brought failure-to-warn, breach of implied warranty, and negligence claims

against a medical device company for withholding risk information, including adverse event reports, from the FDA post-approval. 517 F. Supp. 3d 76, 80 (D. Mass. 2021) (Burroughs, J.). There, the Court held that the plaintiffs failed to identify a state-law duty imposed on medical device manufacturers to report adverse events to the FDA.[7] Id. at 92. The plaintiffs filed an appeal. In January 2022, the First Circuit certified the following question to the Massachusetts Supreme Judicial Court:

> Does a manufacturer's failure to report adverse events to a regulator -- such as one like the FDA -- give rise to liability under Massachusetts law?

Plourde, 23 F.4th at 37.

Pending the Supreme Judicial Court's resolution of this matter, legal questions central to Pietrantoni's failure-to-warn claims remain unsettled. The Supreme Judicial Court is better suited to answer these questions. Dismissing Pietrantoni's allegations as to Corcept's failure to report adverse events to the FDA -- whether as preempted, not cognizable, or factually insufficient -- would therefore be premature.

[7] After Plourde, another session of this Court ruled "that decision persuasive" and held that Massachusetts law does not impose a duty to report adverse events which parallels the FDCA. Muoio v. Livanova Holding USA, Inc., No. 21-11289-LTS, 2021 U.S. Dist. LEXIS 225403, at *4 (D. Mass. Oct. 15, 2021) (Sorokin, J.).

C. Failure to Monitor

Pietrantoni brings two remaining claims premised, at least in part, on Optime and Corcept's failure to monitor her condition while taking Korlym: count two alleges negligent failure to monitor, Compl. ¶¶ 31-38; and count three alleges the same in gross negligence, id. ¶ 40. Corcept and Optime assert that these claims are preempted as "poorly disguised" failure-to-warn claims and, even so, fail on the merits. See Defs.' Mem. 15-16; Defs.' Reply 7. The Defendants' arguments are unavailing; Pietrantoni has sufficiently alleged that Corcept and Optime voluntarily assumed and breached a duty to monitor her.

As an initial matter, Pietrantoni's negligent failure-to-monitor claim is not merely a rephrasing of her failure-to-warn claims. It is predicated on different facts: while her failure-to-warn claims stem from the contents of Korlym's warning label and Corcept's reports to the FDA, her failure-to-monitor claims derive from Corcept's "Patient Care Advocates" and Optime's Support Program for Access and Reimbursement for Korlym -- that is, from the Defendants' undertaking to monitor her health while she was using Korlym. Such allegations are not, as the Defendants seem to argue, preempted. Defs.' Mem. 15-16.

Thus, the only question is whether Pietrantoni has adequately pled the elements of a negligence claim: "duty,

breach of duty (or, the element of negligence), causation (actual and proximate) and damages." Bennett v. Eagle Brook Country Store, Inc., 408 Mass. 355, 358 (1990) (Lynch, J.).

First, the Defendants do not contest for purposes of this motion that Corcept and Optime owed Pietrantoni a duty to monitor her health on Korlym. See Defs.' Mem. 7. Wisely so, as Pietrantoni has plausibly pled that Corcept, by assigning her "Patient Care Advocates" to monitor her health on Korlym, see Compl. ¶¶ 7-11, voluntarily assumed such a duty, see Thorson v. Mandell, 402 Mass. 744, 748 (1988) ("If a person voluntarily assumes a duty or undertakes to render services to another that should have been seen as necessary for her protection, that person may be liable for harm caused because of the negligent performance of his undertaking."); Cottam, 436 Mass. at 323-24 (holding that, although the learned intermediary doctrine prevents a pharmacy from owing a duty to warn customers, "a pharmacy, like any other person or entity, may voluntarily assume a duty that would not otherwise be imposed on it, and thus may voluntarily assume a duty to provide information, advice or warnings to its customers.").

Additionally, Pietrantoni has satisfied the remaining elements of negligence -- breach, causation, and damages -- in stating that her Patient Care Advocates did not instruct her to seek medical care when she stopped having menstrual periods,

causing her to continue using Korlym and ultimately to sustain reproductive injuries. See Compl. ¶¶ 12-13, 36. The Defendants' arguments to the contrary, see Defs.' Mem. 2 (asserting that missed menstrual cycles are an insufficient medical basis for warning a patient); Defs.' Reply 7 (claiming that "no existing data" supports the alleged causal chain), present disputes of fact that do not bear on the present motion.

Pietrantoni has therefore stated a claim for negligent failure to monitor in counts two and three.

VII. CONCLUSION

In summation, the Defendants' motion to dismiss is **ALLOWED** in part and **DENIED** in part. The motion is ALLOWED as to (1) all design-defect claims, as Pietrantoni has represented that she would voluntarily dismiss these claims; and (2) all failure-to-warn claims premised on product labeling, as these claims are preempted by federal law. The motion is DENIED as to (3) all failure-to-warn claims premised on reports to the FDA, because dismissal would be premature given the unsettled state of Massachusetts law; (4) and all failure-to-monitor claims, as Pietrantoni plausibly alleges that the Defendants breached their voluntarily assumed duty to monitor her.

SO ORDERED.

/s/ William G. Young
WILLIAM G. YOUNG
JUDGE
of the
UNITED STATES[8]

[8] This is how my predecessor, Peleg Sprague (D. Mass. 1841-1865), would sign official documents. Now that I'm a Senior District Judge I adopt this format in honor of all the judicial colleagues, state and federal, with whom I have had the privilege to serve over the past 44 years.